UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

REGENERON PHARMACEUTICALS, INC.,

Plaintiff,

vs.

GENENTECH, INC.,

Defendant.

Civil Action No._____

ECF Case

'11 CIV 01156

COMPLAINT

AND DEMAND FOR JURY TRIAL

Plaintiff Regeneron Pharmaceuticals, Inc. ("Regeneron"), for its complaint against Defendant Genentech, Inc. ("Genentech"), alleges as follows:

NATURE OF THIS ACTION

1. This action arises under 28 U.S.C §§ 1331, 2201 and 2202, and the United States Patent Act, 35 U.S.C. § 100 *et seq.*

2. Regeneron brings this action for at least a declaration that no activities relating to the Regeneron VEGF Trap infringe any valid claim of U.S. Patent Nos. 5,952,199; 6,100,071; 6,383,486; 6,897,294; and 7,771,721 (the "Genentech Davis-Smyth Patents").

THE PARTIES

3. Regeneron is a corporation organized and existing under the laws of the State of New York with its principal place of business at 777 Old Saw Mill River Road, Tarrytown, New York. Regeneron was founded in the State of New York in 1988. Regeneron's research and manufacturing facilities are located in the State of New York.

4. Regeneron scientists discovered a novel biopharmaceutical referred to herein as the VEGF Trap. The research that led to the VEGF Trap design is the subject of a number of issued U.S. patents assigned to Regeneron. *See, e.g.*, U.S. Patent No. 7,374,757. The VEGF

Trap is currently in late stage clinical development for a number of ophthalmologic and oncology indications.

5. Regeneron is informed and believes, and thereon alleges, that Genentech is a corporation organized and existing under the laws of the state of Delaware with its principal place of business in South San Francisco, California.

6. Regeneron is informed and believes, and thereon alleges, that Genentech has for many years been licensed, and currently is licensed, to conduct business in this judicial district and that Genentech has for many years conducted a broad array of business, and continues to conduct a broad array of business, within this judicial district. Regeneron is informed and believes, and thereon alleges, that among other things Genentech has for many years sold, and continues to offer for sale and sell, many drug products to residents in this judicial district, whether directly or indirectly through third-party distributors. Regeneron is informed and believes, and thereon alleges, that residents of this judicial district have for many years used, and continue to use, drug products sold and offered for sale by or from Genentech.

JURISDICTION AND VENUE

7. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331; 1338(a); and 2201-2202.

8. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c).

INTRA-DISTRICT ASSIGNMENT

9. Assignment to White Plains is proper pursuant to Rule 21 of the Local Rules for the Division of Business Among District Judges. Regeneron resides in Westchester County, and the claim arose in whole or in major part in Westchester County.

BACKGROUND

DEVELOPMENT OF THE VEGF TRAP

10. The VEGF Trap entered its first phase of human clinical testing in November 2001. In 2007, the VEGF Trap entered its pivotal Phase III clinical testing stage. Phase III studies are designed to develop data that will support a Biologics License Application to the

United States Food and Drug Administration for approval to market a drug in commerce in the United States.

11. On November 22, 2010, Regeneron announced data from Phase III VEGF Trap studies involving treatment of a degenerative eye disorder called wet age-related macular degeneration.

12. Based on the Phase III VEGF Trap study data announced on November 22, 2010, Regeneron submitted a Biologics License Application to the United States Food and Drug Administration on February 18, 2011.

13. An extraordinary investment of resources is necessary to prepare for commercial marketing of the VEGF Trap. For example, commercial marketing requires a complete sales and marketing force. Moreover, arrangements need to be made for the commercial manufacture of the VEGF Trap. Concrete and substantial steps have been taken to prepare for commercial manufacturing and marketing of the VEGF Trap.

14. Uncertainty as to the ability to manufacture for and market the VEGF Trap in commerce risks the extraordinary amounts of money, resources, and employee time invested for commercial manufacturing and marketing of the VEGF Trap.

15. Hundreds of millions of dollars have been spent developing the VEGF Trap. Moreover, a large number of additional clinical trials are ongoing or planned for the VEGF Trap. These trials will cost many millions of dollars and thousands of employee hours to conduct. Uncertainty as to the ability to manufacture for and market the VEGF Trap in commerce puts at risk these resources.

GENENTECH'S DAVIS-SMYTH PATENTS

16. Regeneron is informed and believes, and thereon alleges, that Genentech is the owner of the Genentech Davis-Smyth Patents.

17. In its publicly-available filings with the United States Securities and Exchange Commission ("SEC"), Regeneron disclosed the Genentech Davis-Smyth Patents. Moreover, Regeneron's SEC filings stated that "[a]lthough [Regeneron] do[es] not believe that [VEGF Trap] infringes any valid claim in these patents or patent applications, Genentech could initiate a

lawsuit for patent infringement and assert that its patents are valid and cover [VEGF Trap]" and that "Genentech may be motivated to initiate such a lawsuit . . . in an effort to impair [Regeneron's] ability to develop and sell [VEGF Trap], which represent potential competitive threats to Genentech's VEGF-binding products and product candidates." Regeneron's SEC filings also state that "[a]n adverse determination by a court in any such potential patent litigation would likely materially harm our business by requiring us to seek a license, which may not be available, or resulting in our inability to manufacture, develop, and sell [VEGF Trap] or in a damage award."

18. Regeneron is informed and believes, and thereon alleges, that Genentech maintains that VEGF Trap does not have freedom to operate based on the Davis-Smyth patents. For example, Genentech's former CEO and current Chairman, Arthur Levinson, has indicated, among other things, that Regeneron's VEGF Trap will not have freedom to operate based on the Davis-Smyth Patents and referred to Regeneron's discussion of the threat of the Davis-Smyth Patents in its SEC filings when speaking to major institutional investors. Genentech has also refused to covenant not to sue for infringement involving VEGF Trap based on the Davis-Smyth Patents.

19. Genentech's conduct with regard to VEGF Trap creates a substantial controversy between Regeneron and Genentech with respect to the VEGF Trap of sufficient immediacy and reality to warrant the issuance of a declaratory judgment. There is a definite and concrete dispute between Genentech and Regeneron as to whether any activities relating to the VEGF Trap infringes one or more valid claims of the Genentech Davis-Smyth Patents. Therefore, Regeneron asks this Court to declare that no valid claims of the Genentech Davis-Smyth Patents are infringed or will be infringed based on any activities related to the VEGF Trap.

CLAIM FOR RELIEF

(Declaratory Judgment of Non-Infringement and/or Invalidity of the Genentech Davis-Smyth Patents)

20. Regeneron re-alleges and incorporates by this reference the allegations contained in paragraphs 1 through 19 above.

21. Regeneron seeks a judicial declaration that no acts by any entity related to the VEGF Trap do or will directly infringe or infringe under the doctrine of equivalents, or contribute to or induce the infringement of, any valid claim (including invalidity because of 35 U.S.C. § 101 *et seq.*) of the Davis-Smyth Patents, which declaration is appropriate and necessary.

DEMAND FOR JURY TRIAL

Regeneron demands a trial by jury on all issues in this case properly tried to a jury.

PRAYER FOR RELIEF

WHEREFORE, Regeneron prays for relief as follows:

A. Judgment in its favor on all claims for relief;

B. A declaration that no acts by any entity involving VEGF Trap do or will directly or indirectly infringe any valid claim of the Genentech Davis-Smyth Patents;

C. A declaration that this case is exceptional pursuant to 35 U.S.C. § 285, and an award of attorneys' fees and costs; and

D. For an award of such other and further relief as the Court may deem just and proper.

Dated: February 18, 2011

FITZPATRICK, CELLA, HARPER & SCINTO

By: _____
Scott K. Reed (SR 5803)
Brian V. Slater (BS 7914)
Gregory B. Sephton (GS 6416)
1290 Avenue of the Americas
New York, NY 10104
Tel: 212-218-2100
Fax: 212-218-2200
sreed@fchs.com
bslater@fchs.com
gsephton@fchs.com

Attorneys for Plaintiff
Regeneron Pharmaceuticals, Inc.

Of counsel:

IRELL & MANELLA LLP
Morgan Chu
Jason G. Sheasby
Keith A. Orso
Amir Naini
1800 Avenue of the Stars, Suite 900
Los Angeles, California 90067-4276
Telephone: (310) 277-1010
Facsimile: (310) 203-7199

Of Counsel for Plaintiff
Regeneron Pharmaceuticals, Inc.